

REMARKS

Applicants respectfully request reconsideration of the Examiner's objections and rejections of the claims in view of the foregoing amendments and following arguments.

Claim Rejections – 35 USC §§ 103***Claims 1-11, 18, 19, 21-30, and 37-38***

These claims stand rejected over U.S. Patent No. 4,211,237 to Nagel (hereafter "Nagel") in view of U.S. Published Patent Application No. 2004/0243015 to Smith et al. (hereafter "Smith"). With regard to Claims 1 and 22, Applicants have amended the claims to distinguish over both Nagel and Smith. The amended claims now specify that the events being logged are fetal body movements rather than mere changes in spatial presentation or position. This defines over Nagel and Smith because Nagel and Smith do not teach storing fetal body movements. Support for the amendments can be found in lines 24-27 of page 11 of the specification as filed. See also paragraph [0054] of the specification as published. Note that Applicants use the term "fetal body movements" in a way which excludes fetal heartbeats.

Further, Applicants have amended Claims 1 and 22 by further defining the technique used by the waveform processor. Applicants submit that the amendment defines over the cross correlation function (CCF) technique of Nagel because the described techniques measure movement in different ways. As described in Nagel, the cross correlation analysis uses a group average of the determined waveform. In contrast, the Applicants teach matching the ECG waveforms to one of a series of predetermined templates, determining the number of phase shifts in the ECG waveform, and/or integrating the ECG time trace over a computed baseline to determine the amount of "energy" is contained above and below the baseline and then

determining the changes in the relative energy. Since the claimed processing techniques are fundamentally different from the technique of Nagel, Claims 1 and 22 now define over Nagel.

The claimed difference-determining techniques define over Smith as well. The Examiner cites to paragraph [0131] for the proposition that variations in ECG morphology of fetal heartbeats may be used to indicate presentation or position. Applicants respectfully disagree. Paragraph [0131] states that the variation in heartbeat morphology “*perhaps* indicat[es] fetal presentation and position... and *may* ultimately prove to be an additional diagnostic tool.” Smith presents only theory and provides no enabling disclosure. Smith does not attempt to deduce fetal body movements from the data. As a result, Applicants submit that the amendments to Claims 1 and 22 define over Nagel, Smith, and any combination of them.

Applicants have amended Claims 18, 20, 21, 37, and 39 to reflect the amendments to the independent claims.

Further, Nagel does not attempt to store *successive* changes in the shape of the average fetal ECG complex, $M(t)$, because Nagel does not store more than one average value of the average fetal complex. Instead, column 17, lines 40-55 of Nagel describes locating a fetal ECG complex, averaging the data to come up with an average complex, storing that average complex in memory, and using it as a reference. See the abstract of Nagel for a concise summary of how the average fetal ECG complex is used.

The Applicants, however, teach storing a succession of ECG complex waveforms in a logger (paragraph [0073]) to determine the differences between them (paragraph [0070]). It is this concept of storing successive waveforms that allows the Applicants to determine whether fetal body movements have occurred. Since Nagel teaches storing only one average waveform in

memory, Applicants argue that it is impossible for the apparatus of Nagel to determine whether there has been a change in spatial presentation.

Additionally, Applicants argue that Nagel does not teach use of a logger, but, instead, teaches only memory. The term logger, as used by the Applicants, is capable of storing successive series of data, while the memory described in Nagel is used to store a single average value that is overwritten over and over. Nagel does not disclose this additional capability and, in fact, teaches away from logging long series of data when it emphasizes real time analysis (column 3, lines 51-55) as an advantage of the system. As a result, Applicants argue that Nagel does not teach use of a logger as required in Claims 1, 8, and 9.

Regarding Claims 7 and 27, the Examiner asserted in Claim 1 that Nagel identifies a succession of fetal ECG complexes and, in support, cited item number 33 of Figure 3b. Applicants respectfully disagree and point out that Nagel does not teach a succession of fetal ECG complexes. Instead, Nagel *locates* a fetal ECG complex from the data and stores an average of the fetal ECG complex, $M(t)$. See the description of the CCF at column 5, line 64. When the data matches the average fetal ECG complex, $M(t)$, the CCF gives peak output. However, the technique of Nagel does not *identify* the complex. Stated another way, the CCF shows a strong correlation between the data pattern and a stored average pattern, but because of averaging cannot actually *identify* what the data pattern is.

In contrast, the Applicants' *identify* specific fetal body movement (page 11, lines 24-27; page 15, lines 7-15). As disclosed in the specification, the movements and position can be determined from the fetal complex waveforms (page 13, lines 6-14 and page 14, line 27 to page 15, line 5), integration of the fetal ECG complex (page 13, lines 15-20), or by comparing the ECG complex to a library of waveforms (page 12, lines 25 to page 13, line 5; page 15, lines 6-

15, page 15 line 26 to page 16, line 6). Thus, the claimed invention defines over Nagel's simple correlation of data because the claimed invention identifies and records fetal body movements.

With regard to Claim 10, 11, and 28-30, neither Smith nor Nagel teaches or suggests predetermined fetal ECG complex templates or determining which template best matches each identified fetal ECG waveform.

Regarding Claims 18, 21, and 37, since Nagel and Smith do not teach or suggest determining the number of fetal body movements, Nagel and Smith do not teach a display for displaying a count of the number of fetal body movements or an alarm if the number of fetal body movements falls below a predetermined threshold.

Claims 12-14 and 31-33

These claims stand rejected over Nagel in view of Smith and further in view of U.S. Patent No. 5,088,498 to Beach et al. (hereinafter "Beach"). Claims 12-14 and 31-33 are patentable at least for their dependency on amended Claims 1 and 22.

Regarding Claims 12 and 31, the Examiner asserts that the combination of Smith and Nagel teach the method and apparatus comprise a processing means for detecting phase changes between successive fetal ECG waveforms. Applicants respectfully disagree and reiterate the prior discussion of storing *successive* waveforms. Additionally, the Examiner gives no support for her assertion that Nagel and Smith teach a processing means for detecting phase changes.

Further, Applicants can find no discussion in either Nagel or Smith of phase changes. Nagel refers to a beginning phase during which data is acquired (column 4, lines 33-35) and bringing the sample EKG into identical phase with the fetal EKG (column 6, lines 45-46), but Nagel does not teach measuring the change in the phase of the signal of the fetal heartbeat. As discussed above, paragraph [0131] of Smith does not teach a variation in heartbeat morphology

as an indication of presentation and position since Smith only theorizes this idea but provides no enabling disclosure.

Moreover, the Examiner's combination of Nagel and Smith with Beach is inapposite because Nagel and Smith teach a very different a technology from that used in Beach. Nagel and Smith teach using electrocardiograms, which involve monitoring the electrical signals generated by the body. This is very different from the ultrasound technology of Beach which projects bursts of sound waves into the body and measuring the reflection signature to generate a two dimensional image. The electrocardiogram cannot be used to create an image and only creates a trace showing the electrical activity of the heart. Since the two technologies are unrelated and completely different in nature, it would not have been obvious to combine the phase change detection from the active ultrasound technique with the electrical signals in the passive electrocardiogram technique.

Further, as discussed above, independent Claims 1 and 22 have been amended to include determining fetal body movements, rather than just the fetal heartbeat, as well as the techniques of integrating the ECG signal and matching fetal ECG waveforms to templates. None of these techniques is taught or suggested by Beach.

Regarding Claims 13 and 32, since Nagel and Smith do not teach detecting phase changes and the technology of Beach is unrelated to the ECG waveform, the prior art does not teach the waveform processor comprises means for detecting phase changes of one or more predetermined magnitudes between successive fetal ECG complex waveforms.

Regarding Claims 14 and 33, none of Nagel, Smith, or Beach teaches an event logger. As a result, the prior art does not suggest or make obvious using an event logger to record occasions during which a phase change occurs.

Claims 15-17, 20, 34-36, and 39

These claims stand rejected over Nagel in view of Smith and further in view of U.S. Patent No. 5,596,993 to Oriol et al. (hereinafter “Oriol”). Claims 15-17, 20, 34-36, and 39 are patentable at least for their dependency on amended Claims 1 and 22.

Specifically with regard to Claims 15 and 34, the Examiner asserts that Nagel and Smith teach detecting the changes in the positive and/or negative energy of the fetal ECG waveform, but provides no support for this assertion. Applicants can find no basis in either Nagel or Smith for an alarm associated with the monitored fetal behavior.

Further, Applicants can find no support in Nagel or Smith for detecting the positive or negative energy in the ECG complex waveform relative to a reference as claimed by the Applicants. Paragraph [0126] of Smith teaches band-pass filtering to reduce the wander of a baseline and Nagel teaches finding an average ECG complex, but those operations are entirely different from the integration method described in paragraph [0063] of the Applicants’ specification.

Moreover, the combination of Nagel and Smith with Oriol is inapposite since Oriol teaches tracking *heart rate* as a function of time, rather than the relative portions above and below the ECG baseline. Oriol is not concerned with and does not teach monitoring of the ECG waveforms but is concerned with monitoring the heart rate of the fetus to determine the fetus’s well-being. These are two very different endeavors and, as such, it would not have been obvious to one of skill in the art to combine Oriol with Smith and Nagel.

With regard to Claims 16 and 35, Oriol does not teach using the isoelectric line as the baseline, and with regard to Claims 17 and 36, Oriol does not teach or suggest the reference is derived from a previous or average fetal ECG waveform.

Finally, with regard to Claims 20 and 39, Oriol does not teach an alarm for indicating if the number of fetal body movements during a period of time falls below a predetermined threshold.

Conclusion

The foregoing discussion shows how the claims as now amended patentably define over Nagel, Smith, Oriol and Beech either alone or in combination with any other references which are available to be cited as prior art to this Application. Applicants respectfully request reconsideration of the amended claims on this basis.

This Reply to Examiner's Action is being submitted with a fee for a one month extension of time. It is believed that Applicant's amendments do not necessitate the payment of additional claim fees. Nonetheless, the Commissioner is hereby authorized to charge Deposit Account No. 503982 of Momkus McCluskey, LLC to cover any fee deficiency.

Respectfully submitted,

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